REMARKS

Claims 9 and 17-19 are pending in the present application.

Claims 1-8 and 10-16 have been canceled without prejudice.

New claims 18 and 19 have been added, which are directed to preferred embodiments of claim 9 and 17, respectively, in which the peptide consists of SEQ ID NO:1. Support for these claims can be found in original claim 9 and in the specification at page 4, lines 16-32. No new matter is added by these new claims.

Rejections Under 35 U.S.C. §102.

Claim 9 stands rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Tolstoshev *et al.* (US 5,705,355). This rejection clearly is unwarranted. Claim 9 is directed to a peptide having the sequence of SEQ ID NO: 1 or a portion of SEQ ID NO: 1 consisting of at least 9 consecutive amino acid residues thereof and having a specified MHC class II binding activity. The Office Action alleges that Figure 2(d) of the reference discloses an isolated peptide consisting of 10 consecutive amino acid residues of SEQ ID NO: 1 (i.e., QCVTGEGTPKPE). This contention is incorrect, however. In fact, this reference discloses a sequence comprising QCVTGEGTPKPE with "polyG" (i.e., polyglycine) at the amino terminus thereof, not QCVTGEGTPKPE, *per se*. This is also clear from the description of Figure 2 in column 11, lines 24-40, which states:

> "In FIG. 2:
> (a) corresponds to the hirudin sequence which appears in reference 2 from glu 49 to gly 34,
> (b) corresponds to the sequence of the 48-mer probe synthesized and used for the hybridization,
> (c) corresponds to the sequence of the clone pTG700 in this region, the dots indicating the homologies, and
> (d) corresponds to the amino acid sequence coded in this region of pTG700,[sic]
> It should be noted that the cDNA sequence in pTG700 is incomplete, as it encodes only 28 of the C-terminal amino acids of hirudin, in addition to the 101 bases of the 31 non-translated

sequence preceded by a stop codon in phase. One of the differences relative to the published protein sequence for hirudin is observed in this clone, since glutamic acid replaces glutamine at position 49." (emphasis added).

Thus, sequence (d) in Figure 2 is stated to be the region of hirudin encoded by sequence (c). Both sequence (c) and sequence (d) are written in reverse of the normal convention, i.e., from the 3' to the 5' for (c), and from carboxyl end to amino end for (d). Figure 2(c) shows a nucleotide sequence that begins (from the 5' end) with a series of nine guanosine residues, which encode three glycines, followed by the codon GAC, which encodes an aspartic acid residue, and then codons CAA through GAA, which encode QCVTGEGTPKPE. The sequence shown in Figure 2(d) is set forth, from right to left, as follows: "polyG | QCVTGEGTPKPE-COOH", i.e., with a "|" in place of the encoded Asp. Accordingly, the peptide shown in Figure 2(d) of Tolstoshev *et al.* is GGGDQCVTGEGTPKPE, not QCVTGEGTPKPE, as stated in the Office Action.

In addition, this reference does not disclose a portion of SEQ ID NO: 1 having at least nine amino acid residues and having a potential MHC class II binding activity, wherein the peptide has a stimulation index of > 1.8 in a biological assay of cellular proliferation and said index is taken as the value of cellular proliferation scored following stimulation by the peptide and divided by the value of cellular proliferation scored in control cells not in receipt of the peptide, as required by claim 9.

Since the sequence of Fig. 2(d) in Tolstoshev *et al.* is not a portion of SEQ ID NO: 1, withdrawal of this rejection is warranted.

Claims 9 and 17 also stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schlaeppi *et al.* This rejection is unwarranted, as well. The peptide disclosed in this reference was identified as binding to certain antibodies (i.e., the peptide is a B-cell epitope). In contrast, the peptides of the present claims can best be characterized as comprising T cell epitopes (i.e., having MHC class II binding activity). The Schlaeppi *et al.* reference does not disclose that the peptide has MHC class II binding activity, nor does it disclose that the peptide has a stimulation index of > 1.8 in a biological assay of cellular proliferation and said index is taken as the value of cellular proliferation scored following stimulation by the peptide

and divided by the value of cellular proliferation scored in control cells not in receipt of the peptide, as required by claims 9 and 17. A reference must disclose every element of a claim to be anticipating. See e.g., *In re Bond*, 910 Fed.2d 1360, 21 USPQ2d 1321 (Fed. Cir. 1991). That is not the case here. Furthermore, there is nothing in the applied reference that would have suggested to one of ordinary skill in the art that the disclosed peptide would have had the required MHC class II binding activity. Withdrawal of the rejection is requested.

Conclusion.

For the reasons stated above, claims 9 and 17 are patentable over the applied art. In addition, the applied references clearly do not teach or suggest the peptide or composition of new claims 18 and 19. Reconsideration, allowance of all claims, and early passage of the application to issue is earnestly solicited.

Respectfully submitted,

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